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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,447	05/23/2006	Stuart Greenhalgh	BT/3-22349/A/PCT	4196

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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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12/11/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/580,447	Applicant(s) GREENHALGH ET AL.	
	Examiner SHERIDAN R. MACAULEY	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A response and amendment were received and entered on August 7, 2009. All evidence and arguments have been fully considered. Claims 1-12 and 14-18 are pending and examined on the merits in this office action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-12 and 14-18 stand rejected under 35 U.S.C. 103(a) as obvious over Yamada et al. (US 5,334,519) in view of Seki et al. (US Pat. 5,352,828) and Leonova et al. (Applied Biochemistry and Biotechnology, 2000, 88:231-241, document cited in IDS). Claim 1 recites a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtained from a biocatalysed reaction or fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation process; forming the polymer by polymerizing the ethylenically unsaturated monomer or monomer mixture comprising the ethylenically unsaturated monomer and cellular material and/or components of a fermentation in the presence of a redox and/or thermal initiator and the formed polymer exhibits an intrinsic viscosity of at least 3 dl/g measured using a suspended level viscometer in 1 M sodium chloride at 25 degrees C. Claim 2 recites the process according to claim 1 wherein the ethylenically unsaturated monomer is prepared by providing a substrate that can be converted into an ethylenically unsaturated monomer, contacting the substrate with a biocatalyst which comprises a microorganism or cellular material and thereby converting the substrate into the ethylenically unsaturated monomer containing the cellular material and/or components of a fermentation broth and that this process is carried out inside or outside of an the cell and where it is carried out inside the cell and where it is carried out inside the cell it optionally forms part of the metabolic pathway of the microorganism.

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Claim 3 recites the process according to claim 2 in which the biocatalyst comprises a microorganism and wherein the process is carried out inside the cell and forms part of a metabolic process of the microorganism. Claim 4 recites the process according to claim 1 in which the cellular material comprises whole cells. Claim 5 recites the process according to claim 1 in which the cellular material comprises fractured cellular material. Claim 6 recites the process according to claim 5 in which the fractured cellular material is selected from the group consisting of cell wall material, cell membrane material, cell nucleus material, cytoplasm and proteins. Claim 7 recites the process according to claim 1 in which the components of the fermentation broth are selected from the group consisting of sugars, polysaccharides, proteins, peptides, amino acids, nitrogen sources, inorganic salts (including metal salts), vitamins, growth regulators, enzyme inducers and complex fermentation medium components. Claim 8 recites the process according to claim 1 in which the ethylenically unsaturated monomer is methacrylamide monomer. Claim 9 recites the process according to claim 2 in which the substrate is methacrylonitrile. Claim 10 recites the process according to claim 2 in which the biocatalyst comprises a nitrile hydratase enzyme. Claim 11 recites the process according to claim 1 in which the polymer is a homopolymer or copolymer of methacrylamide. Claim 12 recites the process according to claim 1 in which the ethylenically unsaturated monomer is selected from the group consisting of itaconic acid (or salts thereof), maleic acid (or salts thereof) and methacrylic acid or salts and derivatives thereof. Claim 14 recites the process according to claim 2 in which the substrate is introduced into a vessel and contacted with a biocatalyst and wherein the

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substrate is converted into the ethylenically unsaturated monomer, optionally introduction other monomers into the vessel to form a monomer mixture, subjecting the ethylenically unsaturated monomer or monomer mixture to polymerization conditions, optionally by introducing initiators into the vessel, and thereby forming the polymer inside the vessel. Claim 15 recites a process according to claim 14 in which the biocatalyst is produced inside the vessel. Claim 16 recites a process according to claim 2 in which the biocatalyst comprises microorganisms of the *Rhodococcus* genus. Claim 17 recites the process of claim 16 wherein the microorganism is *Rhodococcus rhodochrous* NCIMB 41164. Claim 18 recites a composition comprising a polymer of an ethylenically unsaturated monomer and further comprising cellular material and/or components of a fermentation broth, wherein the composition is obtained by a process according to claim 1.

5. Yamada teaches a process for preparing an acryamide (an ethylenically unsaturated monomer such as methacrylamide) in which the monomer is obtained from a biocatalysed reaction or fermentation process wherein the substrate (a nitrile such as methacrylonitrile) is contacted by a biocatalyst which comprises a microorganism or cellular material and thereby converted into the monomer (abstract, col. 12, lines 12-40). In the process of Yamada, after the substrate is converted into a monomer, it contains cellular material and/or components of the fermentation medium, such as complex fermentation components (col. 12, lines 12-40). In the process of Yamada, the cellular material may comprise whole cells or fractured cellular material, such as cell wall material, and the process would inherently occur inside of the cell and form part of

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a metabolic process (col. 8, lines 1-39). Yamada teaches that the biocatalyst comprises *Rhodococcus rhodochrous*, which comprises nitrile hydratase (abstract). The process of Yamada occurs inside of a bioreactor or vessel (col. 8, lines 21-25, col. 12, lines 12-40). Yamada teaches that iron may be added to the medium (col. 9).

6. Yamada does not teach the formation of a polymer (homopolymer or copolymer of methacrylamide) in the vessel comprising the ethylenically unsaturated monomer wherein the unsaturated monomer comprises cellular material and/or components of the fermentation broth. Yamada does not specifically teach the claimed viscosity or the use of *Rhodococcus rhodochrous* NCIMB 41164 as the biocatalyst.

7. Seki teaches that polymerization of a solution of acrylamide, an ethylenically unsaturated monomer, will occur under most conditions, such as in the presence of iron (col. 2, lines 13-19, col. 1, lines 45-49).

8. Leonova teaches the production of nitrile hydratase, the enzyme which converts a nitrile to an amide and which is recited in the instant claims, by the organism *Rhodococcus rhodochrous* M8.

9. At the time of the invention, a process of preparing a monomer comprising nearly all of the claimed elements was known, as taught by Yamada. It was further known that solutions of monomers are likely to polymerize if they are not stabilized, as taught by Seki. Since the method of Yamada does not explicitly teach stabilizing the fermentation broth against polymerization, it is either inherent to the teachings of Yamada, or it would occur during routine optimization and experimentation, that polymerization of the fermentation broth would occur. For instance, Yamada teaches that it may be desirable

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to add iron to the medium in order to alter enzyme activity; since Seki teaches that iron may initiate polymerization, one of ordinary skill in the art would have been motivated to modify the teachings of Yamada in the course of routine experimentation in order to result in the polymerization discussed by Seki. Since iron is a metal and may initiate polymerization, it may be considered a redox initiator. One of ordinary skill in the art would have a reasonable expectation of success in polymerizing the fermentation broth taught by Yamada because polymerization of acrylamide solutions is known to occur in such solutions spontaneously, as taught by Seki. The spontaneously produced polymer of Yamada would either be a homopolymer or copolymer of methacrylamide. Seki teaches that the claimed polymer is popcorn-like (col. 5, lines 14-21); it therefore appears that the polymer, once separated from the mixture, would exhibit a solidity that would place it within the claimed viscosity range. Furthermore, although none of the references specifically disclose the use of the claimed strain in the method for the production of polymers, the microbial species *Rhodococcus rhodochrous* was known in the time of the art to perform the biocatalytic reaction recited in the claims. The selection of a strain of a known organism for use in a known method would have been a matter of routine experimentation to one of ordinary skill in the art. One of ordinary skill in the art would have had a reasonable expectation of success in using a strain of *Rhodococcus rhodochrous* in the claimed method because members of the species were known at the time of the invention to be useful for the production of the monomers recited in the claims. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

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10. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed August 7, 2009 have been fully considered but they are not persuasive. Applicant argues that the claimed invention provides an unexpected advantage over the prior art invention because applicant has recognized that a monomer mixture may be subjected to polymerization before removal of cellular material from the fermentation mixture. This is not found to be persuasive, however, because Seki teaches that an unstabilized solution of monomers is likely to polymerize spontaneously under conditions such as those used by Yamada. Therefore, the cited advantage was known in the prior art, i.e., Seki teaches that polymerization was likely to occur in a concentrated monomer mixture and thus could have occurred in the highly concentrated monomer mixture of Yamada as it contained debris from the fermentation process. Furthermore, applicant's showing of unexpected results is limited to a specific type of monomer and polymer and not to the broad range of monomers and resultant polymers recited in the claims; thus, this evidence is not commensurate in scope with the claims. Although applicant further argues that the references do not teach the claimed viscosity, it is noted that Seki teaches that the claimed polymer is popcorn-like (col. 5, lines 14-21); it therefore appears that the polymer, once separated from the mixture, would exhibit a solidity that would place it within the claimed viscosity range. It is noted that if applicant intends to claim that the polymer exhibits a specific viscosity

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without any separation from the reaction mixture, this limitation should be included in the claims. Therefore, applicant's arguments that the cited prior art does not render the claimed invention obvious have therefore not been found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651